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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/812,551

03/29/2004

Claudio Bucolo

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EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/812,551 | Applicant(s) BUCOLO ET AL. | |
| | Examiner Benjamin Packard | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-11,15-17,20,22,25-28 and 47 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-11,20,22,25-28 and 47 is/are rejected.
- 7) ☒ Claim(s) 20 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 07/30/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Status

While the initial election was to a viscoelastic polymer specie of hyaluronic acid, not the combination of hyaluronic acid and hydroxypropylmethyl cellulose, the amendments dated 07/30/2008 have shifted the species to the combination. Therefore, claims 20 and 22 are now examined.

Claim Objections

Claims 20 and 22 are objected to because of the following informalities: both claims at line 2 include the word "yet" before "minimum", instead of the likely intended word, "a". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Claims 1, 6-11, 25-28, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al (US Pregrant Pub 2003/0232089, see IDS dated 06/24/2004) in view of Olejnik et al (US 5,597,599) and Gohzu et al (US 5,013,445).

Singh et al teaches trishydroxymethylaminomethane as a buffering component (paragraph 93) for ophthalmic gum compositions (abstract) where the composition can include hyaluronic acid (paragraph 25) and hydroxypropylmethyl cellulose (paragraph 59). The working examples teach the combination of 0.5% hydroxypropylmethyl cellulose and 0.5% Scleroglucan (page 11, Example 8, Table 5, ID 21). The addition of a tonicity modifier is also taught (paragraph 59).

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Singh et al does not teach the addition of the buffering component or the combination of hyaluronic acid and hydroxypropylmethyl cellulose as a preferred embodiment. Neither does Singh et al teach the addition of a hexahydric alcohol.

Olejnlik et al teaches tonicity adjusting agents are known to include mannitol and sorbitol.

Gohzu et al teaches the use of trishydroxymethylaminomethane in chemical compositions in an amount between 5-100 mM to achieve a pH of from 6.0 to 7.5 (claim 6).

It would be obvious to one of ordinary skill in that to substitute the disclosed “gum” compounds, such as hyaluronic acid for Scleroglucan in the working example ID 21. The addition of the tonicity adjusting agent of Olejnlik would be obvious where the addition of such an additional component was taught. Further, where the addition of buffering agents is disclosed, and the amount would be a matter of routine optimization based on the desire to achieve a physiological pH similar to disclosed in Gohzu et al.

With regard to the viscosity, percentage of quenching, and shear-viscosities, these appear to be conventional in the art, such that their determination would have been obvious to one of ordinary skill in the art using no more than routine experimentation.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al (US Pregrant Pub 2003/0232089) in view of Olejnlik et al (US 5,597,599) and Gohzu et al (US 5,013,445), further in view of Cantoro et al (US 5,770,628).

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Singh et al, Olejnlk et al, and Gohzu et al are discussed above.

Cantoro et al teaches the use of hyaluronic acid and its salts in the range of 500 to 4,000 kD for ophthalmic preparations (abstract, claim 1).

Where the additional art teaches the mass of hyaluronic acid and its salts useful in the same type of composition instantly claimed, an ophthalmic preparation, it would be obvious to one of **ordinary skill to use hyaluronic acids of the disclosed mass..**

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al (US Pregrant Pub 2003/0232089) in view of Olejnlk et al (US 5,597,599) and Gohzu et al (US 5,013,445), further in view of Katz (US 4,287,175).

Singh et al, Olejnlk et al, and Gohzu et al are discussed above.

Katz discloses the use of hydroxypropylmethyl cellulose having a molecular weight of from about 10,000 to 1,000,000 or more, particularly up to about 200,000 and especially about 80,00 to about 125,000 in ophthalmic solutions.

It would be obvious to one of ordinary skill when selecting the hydroxypropylmethyl cellulose to use hydroxypropylmethyl cellulose compounds known to be used in ophthalmic solutions as disclosed in Katz.

Conclusion

No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612